510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 0 6 2013

PHILIPS

InnerSense Esophageal Temperature / Feeding Tube

Submitter's Name and Address

Submitter's Name:	Philips Medical Systems
Division:	PCCI - Medical Consumables and Sensors
Address:	3000 Minuteman Road
City, State, and Zip:	Andover, MA 01810

Contact Person / Submission Correspondent

Name:	Peter Schipelliti
Title:	Sr. Quality and Regulatory Manager
Telephone:	(978) 659-4744
Facsimile:	(978) 659-7712
E-mail:	peter.schipelliti@philips.com

Date of Summary

Date:	March 5, 2013

Manufacturers' Information; Establishment Registration Number.

Establishment name:	Philips Medical Systems
Address:	3000 Minuteman Road Andover, MA 01810
Establishment Registration No.	1218950

New Device Details

Proprietary or Trade Name:	InnerSense Esophageal Temperature / Feeding Tube
Common Name:	Feeding Tube / Temperature Probe
Device Class:	Class II
Device Procode:	FPD
Device CFR:	21 CFR 876.5980
Classification Panel:	Gastroenterology/Urology

Indication for Use

The InnerSense Esophageal Temperature/Feeding Tube is a dual function, single-use sterile device which simultaneously provides continuous monitoring of esophageal temperature and delivers oral medications and/or enteral nutrition in neonatal and pediatric patients oro/nasogastrically, as directed by a physician for up to 30 days. The InnerSense device can be used solely for the purpose of monitoring esophageal temperature in situations where invasive monitoring is indicated.

Product Description

Philips' InnerSense Esophageal Temperature/Feeding Tube is a disposable, single-use, sterile device designed for nasogastric or orogastric placement in neonatal and pediatric patients. It is used to continuously monitor esophageal temperature, deliver oral medications, and/or provide enteral feeding to a patient for up to 30 days. It should be used only under direct supervision of a licensed physician or healthcare provider, according to the hospital standard of care. Note: the temperature probe is auto-located in the distal esophagus when device is placed in accordance with the Insertion steps provided in the Application section of the IFU.

Device Testing / Performance Data

Extensive verification of functional performance has been performed and successfully completed. The proposed device was subjected to numerous verification tests for both the feeding tube attributes and the temperature sensor attributes. Feeding tube related performance tests included tensile strength / pull cycle testing, resistance to liquid leakage under pressure and fluid extraction. Temperature sensor related tests included temperature accuracy and stability. Testing included the standards identified below:

Standards
IEC 60601-1: 1988 + A1:1991 + A2:1995- Medical Electrical Equipment Part 1: General Requirements for Safety
IEC 60601-1-2: 2001+ A1:2004- Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Compatibility – Requirements and Tests
ISO 10993-4: 2002- Biological evaluation of medical devices- Part 4: Selection of Tests for Interactions with Blood
ISO 10993-5: 2009- Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity
ISO 19003-6:2007- Biological evaluation of medical devices – Part 6: Tests for Local Effects After Implantation
ISO 10993-10:2010- Biological evaluation of medical devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity
ISO 10993-11: 2006- Biological evaluation of medical devices – Part 11: Tests for Systemic Toxicity
ISO 10993-17: 2002- Biological evaluation of medical devices- Part 17: Establishment of allowable Limits for Leachable Substances
ISO 10993-18: 2005- Biological evaluation of medical devices- Part 18: Chemical Characterization of Materials
EN 12470-4: 2000+ A1:2009- Clinical Thermometers- Part 4: Performance of Electrical Thermometers for Continuous Measurement
ISO 80369-1:2010- Small-bore Connectors for Liquids and Gases in Healthcare Applications - Part 1: General requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 6, 2013

Philips Medical Systems
% Mr. Peter Schipelliti
Senior Quality and Regulatory Manager
3000 Minuteman Road
ANDOVER MA 01810

Re: K120815
Trade/Device Name: InnerSense Esophageal Temperature / Feeding Tube
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: FPD
Dated: February 19, 2013
Received: February 22, 2013

Dear Mr. Schipelliti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use Statement

PHILIPS

510(k) Number: K120815

Device Name: **InnerSense Esophageal Temperature / Feeding Tube**

Indications for Use:

The InnerSense Esophageal Temperature/Feeding Tube is a dual function, single-use sterile device which simultaneously provides continuous monitoring of esophageal temperature and delivers oral medications and/or enteral nutrition in neonatal and pediatric patients oro/nasogastrically, as directed by a physician for up to 30 days. The InnerSense device can be used solely for the purpose of monitoring esophageal temperature in situations where invasive monitoring is indicated.

Prescription Use (21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120815